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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/702,236	11/05/2003	Donald Hetzel	SENS0002	7940
22862	7590	07/11/2006	EXAMINER	
GLENN PATENT GROUP 3475 EDISON WAY, SUITE L MENLO PARK, CA 94025			SIMS, JASON M	
			ART UNIT	PAPER NUMBER
			1631	

DATE MAILED: 07/11/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No. 10/702,236	Applicant(s) HETZEL ET AL.	
	Examiner Jason M. Sims	Art Unit 1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-27 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-27 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 11/05/2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>9/08/2004</u> . | 6) <input type="checkbox"/> Other: ____.  |

### **DETAILED ACTION**

Claims 1-27 are herein under examination.

#### ***Specification***

The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code on page 4, first paragraph of the specification. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

#### ***Claim Rejections - 35 USC § 101***

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-22 and 25-27 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

Under the Interim Guidelines for Examination of Patent Applications for Patent Subject Matter Eligibility (published in the O.G. notice (1300 OG 142) on 11/22/2005) a method that does not result in a physical transformation of matter MAY be statutory where it recites a concrete, tangible and useful result; i.e. a practical application.

In the instant case, the claims are directed to a method that classifies a subject. In the instant case, the method of claims 1-22 and 25-27 do not result in a physical transformation of matter, nor is any concrete, tangible and useful result produced/recited. Therefore, these claims are not statutory.

#### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claims 1-27 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Applicants cite the word shape with reference to evaluating said profiles in claim 1, but the word "shape" has been deemed vague and indefinite. It is unclear as to what exactly the word "shape" may refer. For example, claim 2, a dependent and further limiting claim states that the blood glucose values comprise a time series. If shape, found in the independent claim, encompasses a broader range than a time series, then what else does it refer?

Claim 1 recites the limitations "said plurality of glucose values" in line 5 and "said profile" in lines 3 and 6. There is insufficient antecedent basis for this limitation in the claim. If applicant intended to refer to plurality of glucose concentrations and glucose profile respectfully, then please amend claim appropriately for the record.

Claims 2-27 are being rejected as being dependent from a rejected claim.

Claims 17-20 are also rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims have variables that are not clearly defined and therefore are deemed vague and indefinite. For example, variables  $P_1$  and  $W_1$  in claim 17 are not defined and are therefore deemed vague and indefinite. It is also unclear as to what influences the weighting factors and how their values are determined and is also deemed as vague and indefinite. Appropriate correction is required.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-13, 16, and 21-27 are rejected under 35 U.S.C. 102(e) as being anticipated by Kalatz et al. (US P/N 6925393).

The claimed subject matter is directed to a method of screening a subject for disorders of glucose metabolism, comprising measuring a glucose profile, evaluating a shape of said profile, classifying a subject based on the evaluation and threshold values, warning and advising subject on health risks associated with classification.

Claims 1, 2, 5, and 22 are taught by Kalatz et al. in the Abstract, in Fig. 3, and at col. 3, lines 66-67 and col. 4, lines 1-19. Kalatz et al. in the Abstract teaches measuring a glucose profile, which comprises a time series and evaluating the profile according to at least one profile. Kalatz et al. at col. 4, lines 5-9, discusses hypo and hyperglycemia as predetermined classes where a subject would be classified as cited by the claims. Kalatz et al. teaches, in Fig. 3, parts of claim 5 wherein a parameter includes area under the curve and over a defined period of time along with a maximum glucose concentration and glucose concentration after elapse of a predetermined time interval.

Claim 3, is taught by Kalatz et al. at col.7, lines 43-45, where Kalatz discusses actual values of blood glucose concentrations.

Claims 4, 8, and 9 are taught by Kalatz et al. at col. 7, lines 22-42. Kalatz et al. discusses how glucose values are proportionate, or relative as cited in the claim, to insulin amounts and are calculated accordingly.

Claim 6 and 7 are taught by Kalatz et al. at col. 3, lines 66-67, col. 4, lines 1-19, col. 7, lines 65-67, and col. 8, lines 1-21. Kalatz et al. discusses a range of normal values and outside this range calls for a warning signal to the subject as being in an abnormal condition. The administration of insulin discussed by Kalatz et al. is indicative of a subject who is diabetic.

Claims 10-13, 16, and 25-27 are taught by Kalatz et al. at col. 9, lines 5-67 and col. 10, lines 1-20. Claim 25 comprises several alternative limitations, such as a noninvasive, minimally invasive, and invasive blood glucose analyzer. Kalatz et al. teaches a minimally and invasive blood glucose analyzer.

Claim 21 is taught by Kalatz et al. at col. 3, lines 66-67 and col. 4, lines 1-19.

Claims 23-24 are taught by Kalatz et al. at col. 8, lines 9-21 and col. 10, lines 15-20. Kalatz et al. discusses advising the subject of screening results through a display which advises the subject on the amount of insulin to administer and allowing the patient to control the concentration levels.

Thus, Kalatz et al. anticipates claims 1-13, 16, 21-27.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 25 is being rejected under 35 U.S.C. 103(a) as being unpatentable over Kalatz as applied to claims 1-13, 16, and 21-27 above, and further in view of Proniewicz et al. (US P/N 6853854).

Claim 25 is directed to methods for obtaining glucose values wherein the method comprises a noninvasive analyzer.

Kalatz does not specifically teach a noninvasive analyzer for obtaining glucose values, but does teach the other limitations of a minimally and invasive blood glucose analyzer.

Proniewicz et al., at col. 2, lines 35-67, teaches using a noninvasive analyzer for obtaining glucose values.

It would have been obvious to one of ordinary skill in the art at the time of the instant application to combine the methods for obtaining and evaluating glucose profiles taught by Kalatz et al. with obtaining glucose values noninvasively as taught by Proniewicz et al. because it is a procedure that has been desirable to have and would be obviously more favorable to many patients who may benefit from this technology.

### ***Double Patenting***

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis

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added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claim 1 is provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claim 1 of copending Application No. 10/702,710. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

Claim 27 is provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claim 43 of copending Application No. 10/702,710. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jason Sims, whose telephone number is (571)-272-7540.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Andrew Wang can be reached via telephone (571)-272-0811.



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Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the Central PTO Fax Center. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR § 1.6(d)). The Central PTO Fax Center number is (571)-273-8300.

Any inquire of a general nature or relating to the status of this application should be directed to Legal Instrument Examiner, Tina Plunkett, whose telephone number is (571)-272-0549.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Av 1631 examiner

6/27/06